OCT 17 2008

510(K) Summary of Safety and Effectivenss

TRIMED, INC. TENODESIS CROSS SCREW, INTERFERENCE SCREW AND SUTURE BEAD

Submitted By:	TriMed, Inc. 25864 Tournament Road, Ste. A Valencia, CA 91355 (800)633-7221
Registration #:	2031009
Prepared By/Contact Person:	Kelli Anderson Phone: (661)312-7150 Fax: (661)254-8485
Proprietary Name:	TriMed Tenodesis Cross Screw, Interference Screw and Suture Bead
Classification:	Class II: Bone Fixation Screws HWC - Section 888.3040 Class II: Fastener, Fixation, Nondegradable, Soft Tissue MBI – Section 888.3040
Summary Preparation Date:	October 10, 2008

I. Indications for Use:

The TriMed Tenodesis Cross Screw and Interference Screw are intended to be used as an aid for fixation of soft tissue grafts to bone. Specific indications for use include:

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand and wrist.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle.

The TriMed Suture Bead is indicated as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated. It may also be used as an adjunct to external and intramedullary fixation systems involving fixation plates and rods, with fracture braces and casting. The Suture Beads are also indicated in ligament and tendon repair and reconstruction associated with fractures and soft tissue reattachment.

The TriMed Suture Bead is not indicated for use within intra-articular sites.

II. Device Description:

The TriMed Tenodesis Cross Screw and Interference Screw are cannulated single use bone screws. The screws are made of implant grade stainless steel, titanium or PEEK, the suture beads are made of implant grade stainless steel or titanium. All products will be available sterile and non-sterile. Variations in implant size, diameter, shape and materials for all components are intended to allow the implants to accommodate variations in patient size, graft size and sites of application.

III. Substantial Equivalence:

K033717 - Transet Fracture Fixation System

Kelli Anderson, MS, RAC
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2008

TriMed, Inc.
% Ms. Kelli Anderson
Regulatory Affairs Specialist
25864 Tournament Road, Suite A
Valencia, California 91355

Re: K081348
Trade/Device Name: Tenodesis Cross Screw, Interference Screw and Suture Bead
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, HWC, HTY
Dated: October 10, 2008
Received: October 14, 2008

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081348

Device Name: TriMed Suture Bead

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081348

Indications for Use

510(k) Number (if known): K081348

Device Name: TriMed Tenodesis Cross Screw and Interference Screw

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Concurrence of CDRH, Office of Device Evaluation (ODE)